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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/620,955	07/21/2000	James S. Huston	ABX-INR/004 CIP	4028

7590 04/10/2003

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EXAMINER	
NICHOLS, CHRISTOPHER J	
ART UNIT	**PAPER NUMBER**
1647	12

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/620,955	HUSTON ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- *The MAILING DATE of this communication appears on th cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-93* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 7-23 (each in part), drawn to a method for inhibiting the formation of intracellular aggregates of selected polypeptides comprising, the step of contacting said polypeptide capable of forming said aggregates with a polypeptide-binding molecule wherein said polypeptide is **huntingtin** and said molecule is an **intrabody**, classification dependent upon agent structure.

II. Claims 1-2 and 6-23 (each in part), drawn to a method for inhibiting the formation of intracellular aggregates of selected polypeptides comprising, the step of contacting said polypeptide capable of forming said aggregates with a polypeptide-binding molecule wherein said polypeptide is **tau** and said molecule is an **intrabody**, classification dependent upon agent structure.

III. Claims 24-33 and 35-38 (each in part), drawn to a method of inhibiting the formation of intracellular aggregates of selected polypeptides in a subject comprising, administering to said subject at risk of having said intracellular aggregates, a polypeptide-molecule wherein said polypeptide is **huntingtin** and said molecule is an **intrabody** and said intrabody is administered as a nucleic acid expressible in said subject, classified in class 514, subclass 44, for example.

IV. Claims 24-30 and 34-38 (each in part), drawn to a method of inhibiting the formation of intracellular aggregates of selected polypeptides in a subject comprising, administering to said subject at risk of having said intracellular

aggregates, a polypeptide-molecule wherein said polypeptide is **tau** and said molecule is an **intrabody** and said intrabody is administered as a nucleic acid expressible in said subject, classified in class 514, subclass 44, for example.

V. Claims 39-42, 44-47, and 49-52 (each in part), drawn to a method of treating a subject having, or likely to have, a neurological disorder comprising, administering to said subject a polypeptide-binding molecule which specifically binds a polypeptide capable of forming a polypeptide aggregate associated with a neurological disorder wherein said neurological disorder is *Huntington's disease* and said polypeptide is **huntingtin** and said molecule is an **intrabody** and said intrabody is administered as a nucleic acid expressible in said subject, classified in class 514, subclass 44, for example.

VI. Claims 39-40, 43-44, and 48-52 (each in part), drawn to a method of treating a subject having, or likely to have, a neurological disorder comprising, administering to said subject a polypeptide-binding molecule which specifically binds a polypeptide capable of forming a polypeptide aggregate associated with a neurological disorder wherein said neurological disorder is *Alzheimer's disease* and said polypeptide is **tau** and said molecule is an **intrabody** and said intrabody is administered as a nucleic acid expressible in said subject, classified in class 514, subclass 44, for example.

VII. Claims 53-58, drawn to a method for identifying a polypeptide-binding molecule or a functional fragment thereof which specifically recognizes a polypeptide, classification dependent upon agent structure.

VIII. Claims 59-66 (each in part), drawn to a method for identifying a compound which specifically recognizes a polypeptide capable of forming undesired intracellular polypeptide aggregates, wherein said polypeptide is **huntingtin**, classification dependent upon agent structure.

IX. Claims 59-63 and 67 (each in part), drawn to a method for identifying a compound which specifically recognizes a polypeptide capable of forming undesired intracellular polypeptide aggregates, wherein said polypeptide is **tau**, classification dependent upon agent structure.

X. Claims 68-71, drawn to an isolated nucleic acid molecule encoding an intrabody, classified in class 536, subclass 23.1, for example.

XI. Claims 72-76 (each in part), drawn to an intrabody, which binds to **huntingtin**, classified in class 530, subclass 300, for example.

XII. Claims 72-73 and 77 (each in part), drawn to an intrabody, which binds to **tau**, classified in class 530, subclass 300, for example.

XIII. Claims 78-83, 85-86, and 90-93 (each in part), a method for inhibiting the formation of intracellular aggregates of a selected polypeptide in animal comprising, immunizing said animal with an immunogen, wherein said immunogen is a polypeptide comprising **huntingtin** and said animal has or is at risk of having *Huntington's disease*, classified in class 424, subclass 184.1, for example.

XIV. Claims 78-80, 84-85, 87, and 92-93 (each in part), a method for inhibiting the formation of intracellular aggregates of a selected polypeptide in animal

comprising, immunizing said animal with an immunogen, wherein said immunogen is a polypeptide comprising **Amyloid Precursor Protein**, classified in class 424, subclass 184.1, for example.

XV. Claims 78-80, 87-88, and 90-93 (each in part), a method for inhibiting the formation of intracellular aggregates of a selected polypeptide in animal comprising, immunizing said animal with an immunogen, wherein said immunogen is an expressible nucleic acid vaccine comprising **Huntingtin**, classified in class 514, subclass 44, for example.

XVI. Claims 78-80, 87, 89, and 92-93 (each in part), a method for inhibiting the formation of intracellular aggregates of a selected polypeptide in animal comprising, immunizing said animal with an immunogen, wherein said immunogen is an expressible nucleic acid vaccine comprising **tau**, classified in class 514, subclass 44, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, II, III, IV, V, VI, VII, VIII, IX, XIII, XIV, XV, and XVI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of using an intrabody to inhibit formation of **huntingtin** aggregates, which is not required by any of the other Inventions.

Invention II requires search and consideration of using an intrabody to inhibit formation of **tau** aggregates, which is not required by any of the other Inventions. Invention III requires search and consideration of using an intrabody administered as a nucleic acid to inhibit formation of **huntingtin** aggregates, which is not required by any of the other Inventions. Invention IV requires search and consideration of using an intrabody administered as a nucleic acid to inhibit formation of **tau** aggregates, which is not required by any of the other Inventions. Invention V requires search and consideration of treating *Huntington's disease*, which is not required by any of the other Inventions. Invention VI requires search and consideration of treating *Alzheimer's disease*, which is not required by any of the other Inventions. Invention VII requires search and consideration of identifying a polypeptide-binding molecule which specifically recognizes a polypeptide, which is not required by any of the other Inventions. Invention VIII requires search and consideration of identifying a polypeptide-binding molecule which specifically recognizes **huntingtin**, which is not required by any of the other Inventions. Invention IX requires search and consideration of identifying a polypeptide-binding molecule which specifically recognizes **tau**, which is not required by any of the other Inventions. Invention XIII requires search and consideration of using **huntingtin as an immunogen**, which is not required by any of the other Inventions. Invention XIV requires search and consideration of using **Amyloid Precursor Protein as an immunogen**, which is not required by any of the other Inventions. Invention XV requires search and consideration of using an immunogen that is an **expressible nucleic acid vaccine comprising huntingtin**, which is not required by any of the other Inventions. Invention XV requires search and consideration of using an immunogen that is an **expressible nucleic acid vaccine comprising tau**, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions X, XI, and XII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Neither Invention XI nor XII is required to make Invention X. Neither Invention X nor XII is required to make Invention XI. Neither X nor XI is required to make Invention XII.

5. Inventions X and each of I, II, VII, VIII, IX, XIII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions X and each of I, II, VII, VIII, IX, XIII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, II, VII, VIII, IX, XIII, and XIV do not recite the use or production of the nucleic acid of Invention X.

6. Inventions X and each of Inventions III, IV, V, VI, XV, and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Invention X can be use in *in situ* hybridization assays (diagnostic assays).

7. Inventions XI and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the huntingtin-specific intrabody can used in an activity assay for huntingtin (biochemical assay).

8. Inventions XII and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the tau-specific intrabody can be used in an activity assay for tau (biochemical assay).

9. Inventions XI and each of II, VII, VIII, IX, XIII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XI and each of II, VII, VIII, IX, XIII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions II, VII, VIII, IX, XIII, and XIV do not recite the use or production of the huntingtin-specific intrabody of Invention XI.

10. Inventions XII and each of I, VII, VIII, IX, XIII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XII and each of I, VII, VIII, IX, XIII, and XIV are unrelated product and methods, wherein each is not required, one for

another. For example, the claimed methods of Inventions I, VII, VIII, IX, XIII, and XIV do not recite the use or production of the tau-specific intrabody of Invention XII.

11. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Amyloid Precursor Protein

b. Presenilin 1

c. Presenilin 2

d. α -2 Macroglobulin

e. Apolipoprotein

f. α-synuclein

g. Huntingtin

h. Prion protein

i. Tau

j. SOD

k. AR

l. Atrophin 1

m. Ataxin 1

n. Ataxin 2

o. Ataxin 3

p. CACNL1A4

q. SCA7

12. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2, 30, 44, 56, 63, 69, 73, 80, 85, and 87 are generic.

13. If applicant selects any one of Inventions I-XVI, one species from the polypeptide group must be chosen to be fully responsive.

14. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. This application contains claims directed to the following patentably distinct species of the claimed invention:

r. Small molecules

s. Peptides

t. Peptidomimetics

u. Antibodies

v. Antibody fragments

w. Intrabodies

18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 7, 35, 49, and 54 are generic.

19. If applicant selects any one of Inventions I-XVI, one species from the polypeptide-molecule binding group must be chosen to be fully responsive.

20. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

21. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

22. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

23. This application contains claims directed to the following patentably distinct species of the claimed invention:

x. Alzheimer's disease

y. Parkinson's disease

z. Huntington's disease

aa. Prion disease

bb. FTD

cc. ALS

dd. SBMA

ee. DRPLA

ff. SCA1

gg. SCA2

hh. SCA3/MJD

ii. SCA4

jj. SCA5

kk. SCA6

ll. SCA7

24. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim is 40 are generic.

25. If applicant selects Invention V or VI, one species from the neurological disorder group must be chosen to be fully responsive.

26. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

27. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

28. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

29. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

30. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search

requirements, and/or different classification, restriction for examination purposes as indicated is proper.

31. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
April 7, 2003

Gary d. Kunz
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